

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

David Mack, *et al.*

Appl. No. 09/525,361

Filed: March 15, 2000

For: **NOVEL METHODS OF DIAGNOSING  
BREAST CANCER, COMPOSITIONS,  
AND METHODS OF SCREENING FOR  
BREAST CANCER MODULATORS**



Art Unit: 1634

Examiner: Diana B. Johannsen

Atty. Docket: 05882.0129.CPUS03

Confirmation No.: 9370

**Information Disclosure Statement**

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that

had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- ☐ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required, or
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
  - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
  - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or
  - ☐ c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Attached is our check in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p), and
  - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than

three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or


- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 05882.0129.CPUS03.

Respectfully submitted,

Date: December 12, 2003

  
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<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary) <b>PTO FORM 1449</b>	ATTY. DOCKET NO. 05882.0129.CPUS03	APPLICATION NO. 09/525,361
	APPLICANT David Mack, et al.	
	FILING DATE March 15, 2000	GROUP

U.S. PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	1.	WO 98 45328	10/15/98	PCT			X	
	2.	WO 99/33869	07/08/99	PCT			X	
	3.	WO 00/22130	04/20/2000	PCT			X	
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)								
	4.	Invitation to Pay Additional Fees with Partial Search Report						
	5.	Database Swissprot 'Online! "ODPA human" retrieved from EBI Database accession no. P08559 XP002254869 (1992)						
	6.	Bertucci, et al., "Gene expression profiling of primary breast carcinomas using arrays of candidate genes," <i>Human Molecular Genetics</i> 9(20):2981-2991 (2000)						
	7.	Burger, et al., "Detection of novel genes that are up-regulated (Di12) or down-regulated (T1A12) with disease progression in breast cancer," <i>Medline</i> XP002217698 (1998)						
	8.	Martin, et al., "Linking Gene Expression Patterns to Therapeutic Groups in Breast Cancer," <i>Cancer Research</i> 60:2232-2338 (2000)						
	9.	Watson, et al., "Isolation of Differentially Expressed Sequence Tags from Human Breast Cancer," <i>Cancer Research</i> 54(17):4598-4602 (1994)						
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.